

### **REMARKS**

Claims 1-9 are currently pending in this application (claims 10-17 being previously withdrawn). Claims 1 and 9 are amended by this response.

#### **Summary of the Action**

Claims 1-9 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,713,856 to Eggers et al. (hereinafter “Eggers”). Claims 1-9 are also rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Published Application No. 2003/0029453 to Smith et al. (hereinafter “Smith”). Finally, claims 1-9 are rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Published Application No. 2003/0125662 to Bui (hereinafter “Bui”).

All claims are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims of U.S. Patent Nos. 7,229,430 and 7,247,154. All claims are also provisionally rejected on the same ground as being unpatentable over claims of copending Application Nos. 10/285,689; 10/677,482; 10/677,481; 10/439,328; 11/783,546; and 10/265,639.

#### **Obviousness-Type Double Patenting**

The Office Action rejected claims 1-9 for obviousness-type double patenting based on U.S. Patent Nos. 7,229,430 and 7,247,15 and provisionally rejected claims 1-9 based on copending U.S. Patent Application Nos. 10/285,689; 10/677,482; 10/677,481; 10/439,328; 11/783,546; and 10/265,639. Applicant submits that the subject matter being claimed in claims 1 and 9, at least as amended, is not fully disclosed in any of the listed patents or applications. Therefore, Applicant respectfully requests that the rejections be withdrawn.

#### **Applicant's claims are allowable over the prior art**

The Office Action rejects claims 1-9 under 35 U.S.C. § 102 as being anticipated by Eggers, Smith, and Bui. These rejections are respectfully traversed.

To establish a *prima facie* case of anticipation under 35 U.S.C. § 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. MPEP 2131. Applicant respectfully submits that this criterion has not been met for the references as applied to the claims of the present invention.

Eggers

Eggers discloses a *patient controlled* medication delivery system. More specifically, Eggers discloses a modular patient care system that allows various functional units (150) to be attached to a central interface unit (100) having a display (102).

Claim 1 of the present invention recites, in part, “an electronic controller . . . wherein said electronic controller receives said signals and in response to said signals controls the effector in accordance with the parameters.” Applicant respectfully submits that Eggers fails to teach or suggest the concept of an electronic controller controlling an effector in response to signals from patient health monitors.

Eggers discloses the concept of delivering drugs to patients with certain electronic functional units (such as infusion pump units 150A) and the concept of monitoring patient physiological conditions with other types of electronic functional units (such as an electrocardiograph). See Eggers, column 4, last paragraph. However, the invention of Eggers employs the separate and independent operation of these concepts. Eggers also discloses the concept of storing an event history for the purpose of updating patient records or troubleshooting. See Eggers, column 12, last paragraph. However, the invention of Eggers fails to disclose the concept of “an electronic controller . . . wherein said electronic controller receives said signals and in response to said signals controls the effector in accordance with the parameters,” as recited in claim 1. Eggers discloses a system that simply stores information for the purpose of static calculations of drug dosage, flow rate, or bolus dosage based on initial patient parameters but fails to disclose a system wherein an electronic controller controls an effector in response to patient health monitor signals.

Eggers discloses a system of an interface unit and attached functional units wherein the interface unit provides power and controls command and data flow to, from, and between the functional units. See Eggers, column 6, lines 38-67 and column 7, lines 10-20. However, the control of the interface unit in Eggers does not include responsive drug delivery or effector control, but rather provides power and relays user commands and data for display.

Furthermore, the invention as presently claimed also cannot be anticipated by Eggers because Eggers does not disclose accessing parameters of at least one of said monitored patient physiological conditions. Therefore, it is further evident that Eggers cannot possibly disclose the

control of an effector in accord with monitored patient condition and the parameters.

By way of example, starting at Column 8, line 55, Eggers discloses that functional unit 150 can include an infusion pump unit 150A having a processor and memory that "allows the pump unit to perform the calculations required for a designated infusion using infusion data entered by the user." In this portion of its disclosure, Eggers generally discloses a drug delivery controller that is capable of altering drug flow to a patient. As will be readily appreciated by one skilled in the art, however, this is not control of an effector in accord with parameters of at least one of said monitored patient physiological conditions as is required by the present claims. The infusion pump unit 150A taught in Eggers is merely a "pumping unit for basic fluid infusion" (See Eggers, Col. 5, ll. 17-64) that accepts data (i.e., desired volume to be infused ("VTBI"), drug identity, drug concentration, patient demographic data, etc) that is manually input by a user and then automatically calculates an appropriate pump flow rate according to a stored VTBI algorithm (see Eggers Col. 14, ll. 17-64). As will be readily appreciated by one skilled in the art, a VTBI algorithm is not the parameters as properly employed in particular embodiments of the present invention.

The disclosed infusion pump unit 150A in Eggers merely takes data manually input into the unit by a user (which includes desired dosage amount or VTBI), calculates an appropriate pump flow rate from this input, and then operates the pump at that calculated fixed rate for a predetermined amount of time. (See Eggers Col. 15, l. 63 through Col. 16, l. 58). Such known infusion pumps are not controlled by a electronic controller that makes decisions in accord with parameters regarding how to control an effector as is claimed.

By way of additional example, Eggers states at column 13 lines 11-19 that the disclosed patient care system could be connected to an external device in a computer control mode to implement closed-loop drug delivery. While, at best, this bare statement indicates that Eggers contemplated the possibility of an external device to control drug delivery, it still does not disclose use of parameters according to the present invention. Nowhere does Eggers disclose, teach, or suggest that patient health monitor feedback should be compared with parameters that represent patient physiological conditions to reach a decision as to how to control an effector in response to such feedback.

Finally, claim 1 recites, in part, "two or more patient health monitor devices adapted so as

to be coupled to a patient and so as to each generate a signal reflecting one or more physiological conditions of the patient wherein the operating principle of each of said monitors is different and at least two of said patient health monitor devices provide orthogonally redundant information regarding at least one of said physiological conditions.” Applicant respectfully submits that Eggers also fails to teach or suggest the concept of orthogonal redundancy.

For the above reasons, it is clear that Eggers does not disclose accessing parameters of patient physiological conditions, control of an effector in accord with parameters, or orthogonal redundancy as recited by claim 1. Similar limitations are recited by claim 9. In this regard, the rejections of the claims based upon Eggers fail to meet the standard for a *prima facie* anticipation rejection as these references fail to teach all elements of the claims.

In light of the above amendments and remarks, it is respectfully submitted that the outstanding rejection of the above claims as being anticipated by Eggers is improper. Thus, Applicant respectfully submits that claims 1 and 9 are not anticipated by Eggers.

Claims 2-8 depend directly or indirectly from claim 1 and incorporate the limitations of the base claim. Thus Applicant respectfully submits that claims 2-8 are not anticipated by Eggers for at least the reasons recited with respect to claim 1 above.

### Smith

Smith discloses an emergency life support system including monitors and a patient ventilator. Smith, Abstract. Smith does not teach or suggest a sedation and analgesia system, control of an effector based on signals from patient health monitors, nor orthogonal redundancy as claimed in claims 1 and 9 of the present invention.

Smith does not disclose drug delivery or pain relief outside of paragraph 0013, which explains that Smith supports injuries common in combat, including those that “may occur or be related to sedation, anesthesia, or shock.” Smith also fails to disclose the use of two or more patient health monitor devices where at least two of said patient health monitor devices provide orthogonally redundant information. Thus Smith fails to teach or suggest all the elements of independent claims 1 and 9 of the present invention. In this regard, the rejections of the claims based upon Smith fail to meet the standard for a *prima facie* anticipation rejection as these references fail to teach all elements of the claims.

In light of the above amendments and remarks, it is respectfully submitted that the outstanding rejection of the above claims as being anticipated by Smith is improper. Thus, Applicant respectfully submits that claims 1 and 9 are not anticipated by Smith.

Claims 2-8 depend directly or indirectly from claim 1 and incorporate the limitations of the base claim. Thus Applicant respectfully submits that claims 2-8 are not anticipated by Smith for at least the reasons recited with respect to claim 1 above.

#### Bui

Bui (as described in the Abstract) discloses a medical treatment administration system for delivering a medical treatment to a patient. The system has a medical device, an electronic processor coupled to the medical device, and a sensor coupled to the processor. Based on signals from the sensor, the processor regulates the distribution of medical treatment to the patient over a period of time. However, Bui does not disclose orthogonal redundancy as claimed in claims 1 and 9 of the present invention.

Claim 1 recites, in part, “two or more patient health monitor devices adapted so as to be coupled to a patient and so as to each generate a signal reflecting one or more physiological conditions of the patient wherein the operating principle of each of said monitors is different and at least two of said patient health monitor devices provide orthogonally redundant information regarding at least one of said physiological conditions.” Claim 9 recites a similar limitation. Bui discloses the use of multiple sensors in series or parallel (see Bui, paragraph 0055), but Bui does not disclose multiple monitors providing orthogonally redundant information.

Thus Bui fails to teach or suggest all the elements of independent claims 1 and 9 of the present invention. In this regard, the rejections of the claims based upon Bui fail to meet the standard for a *prima facie* anticipation rejection as these references fail to teach all elements of the claims.

In light of the above amendments and remarks, it is respectfully submitted that the outstanding rejection of the above claims as being anticipated by Bui is improper. Thus, Applicant respectfully submits that claims 1 and 9 are not anticipated by Bui.

Claims 2-8 depend directly or indirectly from claim 1 and incorporate the limitations of the base claim. Thus Applicant respectfully submits that claims 2-8 are not anticipated by Bui

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for at least the reasons recited with respect to claim 1 above.

Appropriate reconsideration and withdrawal of the rejections of claims 1-9 under 35 U.S.C. § 102 is respectfully requested.

Conclusion

In view of the foregoing, Applicant respectfully requests that the Examiner examine the application upon the merits, and that the above remarks be fully considered in conjunction therewith. Timely allowance of all currently pending claims and the issuance of a Notice of Allowance are requested.

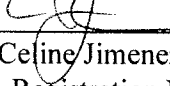
Applicant has filed this Response and Amendment without increasing the number of claims above the number previously submitted or paid for. Accordingly, no additional claims fees are believed to be due at the present time. If such fees or any other fees associated with the filing of this paper are due at this time, please charge the fees to our Deposit Account No. 50-1349. Also, please credit any overpayments to Deposit Account No. 50-1349.

The Examiner is invited to contact Applicant's undersigned representative via telephone if such would expedite prosecution of this application toward allowance.

Respectfully submitted,

Dated: August 8, 2008

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